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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,641	07/20/2001	Makoto Asakawa		6517

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/762,641	ASAKAWA ET AL.
	Examiner David Guzo	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) 7-16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: <u>Yours truly</u> |

Detailed Action

A substitute specification (excluding the claims) in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

It is noted that this application appears to claim subject matter disclosed in prior copending Application No. PCT/JP/04333, filed 8/10/99. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied

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by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

The preliminary amendment filed 7/20/01 has only been entered in part. The amendments to claims 6-13 **have not been entered** as applicants have presented only a marked-up copy of the claims without the required clean copy of the claims (See CFR 1.121). Claims 6-13 are examined as originally presented. New claims 15-16 have been entered.

Claims 7-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7-16 have not been further treated on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mottet et al.

Applicants and Mottet et al. (cited by applicants, *Virology*, 1996, Vol. 221, pp. 159-171, see whole article, particularly Fig. 1 and the paragraph bridging pages 166-168) recite a RNA molecule (from Sendai virus) that can form a complex capable of cell infection, autonomous RNA replication and contact infiltration but is incapable of dissemination wherein said RNA comprises genes involved in contact infiltration and autonomous RNA replication but contains no or inactivated genes involved in dissemination. Mottet et al. therefore teaches the claimed invention.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Magai et al. (EP 0 864 645, published 5/9/97).

Applicants and Magai et al. (Cited by applicants, see whole document, particularly pp. 5-6 and Claims 1-10) recite a RNA molecule (from Sendai virus and containing a foreign gene) that can form a complex capable of infection, autonomous RNA replication and contact infiltration but is incapable of dissemination wherein said RNA comprises genes involved in contact infiltration and autonomous replication but contains no or inactivated genes involved in dissemination. Magai et al. therefore teaches the claimed invention.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 76, 79-82 and 84-88 of copending Application No. 09/070,938. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an RNA molecule (which can be from Sendai virus and can contain foreign sequences) that is capable of forming a complex capable of cell infection and autonomous replication but is not capable of dissemination wherein the RNA comprises genes associated with cell infectivity and autonomous replication but has genes associated with dissemination (i.e. the M gene) deleted or inactivated. The instant claims differ from those recited in the '938 application in that the RNA is recited as being capable of contact infiltration; however, viruses such as wild type Sendai virus are normally capable of contact infiltration when genes regulating dissemination (such as the M protein encoding gene) are deleted or inactivated. It therefore must be considered that the ability of the RNA from (-) strand RNA viruses such as Sendai virus to be capable of contact infiltration is an inherent property of the RNA from these viruses. It would have been obvious for the ordinary skilled artisan to generate the

claimed RNAs because said RNAs are an integral part of the complexes claimed in the '938 application and would be required to practice the claimed invention in the '938 application. The ordinary skilled artisan would have been motivated to generate the instant RNAs because said RNAs are an essential component of the complexes recited in the '938 application and are essential for delivering the foreign gene to the target cell. Given the teachings of the claims in the '938 application and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 are directed to an invention not patentably distinct from claims 76, 79-82 and 84-88 of commonly assigned application 09/070,938. Specifically, the claims are not patentably distinct for the reasons cited in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/070/938, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the

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examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being obvious over Nagai et al. (09/070,938).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

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application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claims are obvious over 09/070,938 for the reasons outlined in the above obviousness type double patenting rejection of claims 76, 79-82 and 84-88.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claims read on a genus of RNA molecules that are capable of forming a complex capable of cell infection, autonomous replication and contact infiltration but incapable of dissemination wherein genes associated with dissemination are deleted or inactivated. Applicants provide a written description of RNAs with the recited characteristics wherein said RNAs are from (-) strand RNA viruses.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus. In the instant case, applicants provide a single example of the claimed invention (involving the (-) stranded Sendai virus) and provide no description of the characteristics of non (-) RNA molecules with the recited characteristics. Applicants claim the RNAs by functional characteristics only without providing a correlation between the structure of the RNAs and their function. For example, applicants provide no description of any non-viral RNAs or (+) strand RNA viruses with the recited characteristics. Given the large size of the genus and the diversity of RNA molecules encompassed within said genus, it must be considered that the disclosure of a single example would not be sufficient to convince the skilled artisan that applicants were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague in that applicants claim a RNA molecule that forms “a complex” capable of cell infection, etc... It is unclear what the other components of the “complex” consist of or whether the complex consists only of the recited RNA molecules.

Claim 2 is vague in the recitation of the phrase “...genes encoding a protein...” because it is unclear how many genes are involved in encoding the recited protein. Generally, in negative strand viruses, a single gene encodes a single protein. Claim 2 is vague in that there is no antecedent basis for the term “the envelope and the virus core” in claim 1.

Claims 4-5 are vague in the recitation of the term “derived from” because it is unclear how closely related the final RNA molecule is to the starting material it was “derived from”. The metes and bounds of the claimed subject matter are therefore unclear.

Claim 5 is vague in the recitation of the phrase “...comprises no or inactivated gene encoding M protein” because the syntax of the claim is confusing. Redrafting the claim to recite “...Sendai virus and wherein said RNA molecule lacks a gene encoding M protein or comprises an inactivated gene encoding M protein.” would be remedial.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-

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1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
September 19, 2002

DAVID GUZO
PRIMARY EXAMINER
